

PATENT  
PC7250AMEB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED  
CENTRAL FAX CENTER

SEP 06 2005

IN RE APPLICATION OF: : EXAMINER:  
DOUGLAS J. M. ALLEN ET AL. :  
CONTINUATION OF: :  
SERIAL NO.: 07/449,961 : ART UNIT:  
FILED: DECEMBER 21, 1992 :  
FOR: AZITHROMYCIN DIHYDRATE :

I hereby certify that this  
correspondence is being  
deposited with the United States  
Postal Service as First Class mail  
in an envelope addressed to:  
Commissioner of Patents and  
Trademarks, Washington, D.C.  
20231, on this 28<sup>th</sup> day of

Hon. Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Sir:

DECLARATION UNDER 37 C.F.R. § 1.132

By Theresa B. Buehl

I, Helen R. Hangac, declare that:

1. I received a Ph.D. degree in Analytical Chemistry  
from Duke University in 1982.

2. I have been employed by Pfizer Inc, assignee of  
the above-identified application, in the Analytical  
Research and Development Department at Groton, Connecticut  
since 1982. My current position is that of project leader  
in which I am responsible for analytical procedures  
performed on experimental pharmaceuticals, including  
azithromycin.

3. I am familiar with the subject matter of the  
above-identified application.

4. A series of experiments were performed under my  
direction by Near Infrared Spectroscopy and X-ray Powder  
Diffraction to determine if significant amounts of  
azithromycin dihydrate (Type A) were present in  
azithromycin (Type B) a hygroscopic monohydrate. The  
azithromycin (Type B) lots examined/used in the studies  
are listed in Table 1. The azithromycin (Type B) lots  
utilized in the experiments were manufactured using three  
different crystallizing solvent systems, i.e.,  
ethanol/water, acetone/chloroform, and acetone. All lots  
of azithromycin (Type B) listed in Table 1 have been shown  
to be equivalent using infrared spectrometry, and/or X-ray

-2-

diffraction and are equivalent to the original sample described by Bright in U.S. Patent 4,474,768.

| AZITHROMYCIN TYPE B LOTS EXAMINED/USED<br>IN NEAR IR AND X-RAY STUDIES         |        |                    |
|--|--------|--------------------|
| LOT NUMBER   | TYPE   | SOLVENT SYSTEM     |
| 1022107  | TYPE B | ACETONE/CHLOROFORM |
| 4351080  | TYPE B | ACETONE/CHLOROFORM |
| 1039117  | TYPE B | ACETONE/CHLOROFORM |
| 4101026  | TYPE B | ETHANOL/WATER      |
| 13,577-209-1F  | TYPE B | ETHANOL/WATER      |
| 4101036  | TYPE B | ACETONE/CHLOROFORM |
| 17,419-216-3   | TYPE B | ACETONE            |
| 11,860-18-1 <sup>1</sup>   | TYPE B | ETHANOL/WATER      |
| <sup>1</sup> Sample referenced in Bright, U.S. Patent<br>4,474,768, Example 3. |        |                    |

5. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

April 19, 1994  
Date

Helen H. Hangac  
Helen H. Hangac

VegN7250AHAN.MEB